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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/939,209 | 08/24/2001 | Pat Ressler Levitt | 00-539-US | 3394 |

7590

05/16/2005

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EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/939,209

Applicant(s)

LEVITT ET AL.

Examiner

Celine X. Qian Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,18,20 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,18,20 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 5, 18, 20 and 46 are pending in the application.

This Office Action is in response to the Amendment filed on 2/24/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/05 has been entered.

Response to Amendment

The rejection of claims 18 and 20 under 35 U.S.C. 112 1st paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1, 5, 18, 20 and 46 under 35 U.S.C. 112 1st paragraph (written description) is moot in light of the new grounds of rejection under new matter.

Claims 18 and 20 are rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 5, 18, 20 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected to for containing new matter. The amended claims recites fragment of SEQ ID NO:3 comprises variations, wherein the fragments are at least 20 nucleotides in length. This limitation is not supported by the instant specification because the specification fails to disclose such claimed fragments. Applicants are invited to point to specific teaching in the specification that supports the amendment to the claims. Absent evidence from the contrary, such recitation constitutes new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “a DNA sequence corresponds to SEQ ID NO:3” renders the claims indefinite because it is unclear what type of DNA sequence is considered “correspond” to SEQ ID NO:3. In other words, does it mean the DNA sequence is SEQ ID NO:3 or merely share sequence similarity to SEQ ID NO:3 considered correspond to SEQ ID NO:3? If only sequence

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homology is required, what the percentage of similarity has to be? The metes and bounds of the claims cannot be established.

Specification

The disclosure is objected to because of the following informalities: The specification discloses two primer sequences on page 35 as SEQ ID NO:3 and 4. However, according to the paper listing and CRF, SEQ ID NO:3 is a genomic sequence of 20300 base pair in length, and SEQ ID NO:4 is a sequence of 480 base pair in length. They are not same as the primer sequence disclosed in page 35. It is then unclear which is the real SEQ ID NO:3 and 4.

Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

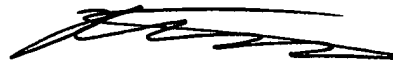
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER



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AMENDMENTS TO THE CLAIMS:

1. (Currently amended) An isolated and substantially purified DNA sequence comprising SEQ ID NO:3, wherein SEQ ID NO:3 ~~containing~~ includes at least one variation selected from the group consisting of:

a T at nucleotide base number 4121 of SEQ ID NO:3;

a C at nucleotide base number 4621 of SEQ ID NO:3;

a T at nucleotide base number 4970 of SEQ ID NO:3;

a C at nucleotide base number 11056 of SEQ ID NO:3; and

a T at nucleotide base number 12145 of SEQ ID NO:3,

or ~~contiguous portions thereof~~ a fragment of SEQ ID NO:3, wherein said fragment includes at least one of said variations and is at least 20 nucleotides in length.

2. (Cancelled)

3. (Cancelled)

4. (Cancelled)

5. (Previously presented) A hybridization probe comprising the DNA sequence of claim 1 and a detectable label.

6. (Cancelled)

7. (Cancelled)

8. (Cancelled)

9. (Cancelled)

10. (Cancelled)

11. (Cancelled)

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